

### REMARKS

In the Office Action, claims 1, 4, 5 and 16 were rejected under 35 USC §103(a) as being anticipated by GB 2171906 in view of U.S. Patent No. 5,830,463. Claims 1, 4 and 5 were rejected under 35 USC 103(a) as being unpatentable over U.S. Patent No. 5,824,334 in view of U.S. Patent No. 5,830,463. Claims 6-9 and 12-15 were rejected under 35 USC 103(a) as being unpatentable over GB '906 in view of U.S. Patent No. 5,830,463 and further in view of U.S. Patent No. 5,733,574. Claims 6, 7, 9 and 11 were rejected under 35 USC 103(a) as being unpatentable over GB '906 in view of US 5,830,463 and further in view of U.S. Patent No. 6,358,060. Claim 10 was rejected under 35 USC §103(a) as being unpatentable over GB '906 in view of U.S. Patent Nos. '463 and '574 and '060 and further in view of GB 2 299 756.

The first rejection over GB '906 in view of U.S. Patent No. 5,830,463 is not well founded. The GB '906 patent discusses an orifice provided in the encapsulating agent through which a pharmaceutically effective compound is forced by osmotic pressure. This does not appear to be particularly relevant with respect to claim 1.

With regard to the second rejection in light of U.S. Patent No. 5,824,334 and U.S. Patent No. 5,830,463, none of the examples disclosed in U.S. Patent No. 5,830,463 relate to encapsulation. The examples all refer to the use of recombinant

yeast to express a recombinant molecule on its surface to stimulate an immune response in an animal. This patent has nothing whatsoever to do with physically encapsulating a molecule within a microcapsule where the microcapsule is a yeast cell. Indeed the document states that the recombinant molecule is presented at the cell surface of the yeast. This is not encapsulation in even its broadest meaning. Furthermore, the document does not disclose nor does it suggest the "nicotine" can be encapsulated within a yeast cell much more the nicotine being capable of release on contact of the microcapsules with a fatty tissue of the buccal cavity.

With regard to U.S. Patent No. 5,824,334, it specifically states at column 10, lines 10-11 that microencapsulated drugs are nicotine particles or droplets which have been coated with a protective coating material. In contrast the present invention concerns the use of yeast cells whereby the nicotine is added to a slurry comprising the yeast cells under conditions whereby the nicotine is taken up by the already formed microcapsules, i.e. yeast cells. The yeast cells cannot be used to coat the nicotine. This simply would not work.

According to U.S. Patent No. 5,824,334, the term "microencapsulation" is stated as meaning the formation of a protective coating around droplets of nicotine. This document clearly teaches away from the present invention which, as stated

above, requires the nicotine to be absorbed by the already formed yeast cell microcapsule.

There is no motivation for one of ordinary skill in the art to combine the two documents. Indeed, even if the Examiner maintains that the skilled person would combine the two documents, one of ordinary skill would not arrive at the present invention. However can one coat nicotine with a protective coating of yeast cells.

Accordingly, claims 1 and 4-15 are patentably distinguished over the references relied upon in the rejection of the claims. New claims 17-22 have been added to include the feature in the claims of a loading up of between 25 to 65 percent by weight of nicotine into the cells. This would also appear to distinguish over the prior art of record.

Based on the foregoing amendments and remarks, it is respectfully submitted that the claims in the present application, as they now stand, patentably distinguish over the references cited and applied by the Examiner and are, therefore, in condition for allowance. A Notice of Allowance is in order, and such favorable action and reconsideration are respectfully requested.

However, if after reviewing the above amendments and remarks, the Examiner has any questions or comments, he is cordially invited to contact the undersigned attorneys.

Respectfully submitted,

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